STEVEN A. THOMPSON
Executive Director

OKLAHOMA DEPARTMENT OF ENVIRONMENTAL QUALITY

BRAD HENRY
Governor

April 12, 2010

The Honorable Edward J. Markey
Chairman
Subcommittee on Energy and Environment
House of Representatives
Washington, DC 20515-2107

Dear Chairman Markey:

This is in response to your letter, dated March 18, 2010, to the Oklahoma Department of Environmental Quality (DEQ) requesting information on our regulations concerning release of patients administered therapeutic doses of Iodine-131. We have attempted to answer all of the questions posed in your letter, based on reviews of our compliance and enforcement records. Our state radiation management regulations can be found on our web page at http://www.deq.state.ok.us/rules/410.pdf. Our program was last evaluated by the Nuclear Regulatory Commission in 2006 and was found to be adequate to protect public health and safety and compatible with the NRC's program. Our responses to your questions are attached. If you have any further questions, please contact me at (405) 702-7100.

Sincerely yours,

Steven A. Thompson
Executive Director
Department of Environmental Quality

ST/ks

Attachments

1. *How many I-131 licensee facilities are overseen by your state?*

   Presently there are 46 facilities in Oklahoma licensed to use unsealed byproduct material requiring a written directive under the provisions of 10 CFR 35.300. Nearly all of these facilities use Iodine-131 therapeutically.

2. *How often does your state perform sampling inspections each of these I-131 licensee facilities?*

   Facilities which are licensed for use of unsealed byproduct material requiring a written directive are inspected at least once every three years. Some of these facilities may be inspected more frequently depending on what other licensed activities they conduct.

3. *What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.*

   Inspections are conducted in accordance with the procedures described in the NRC's Inspection Manual, Chapter 2800. We do not use standardized checklists; however, the inspection must address all of the points listed in the DEQ inspection report form. A copy of this form is attached. Patient release criteria is included in Part II, Item 6.

4. *NCRP 155, includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients". For a patient receiving 175 millicuries of 1-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?*

   We have adopted the criteria contained in 10 CFR 35.75 (Release of individuals containing unsealed byproduct material or implants containing byproduct material). This includes the requirement to provide released patients with written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. In response to your letter, we conducted a telephonic survey of state radiopharmacies, and found that less than 5% of the I-131 therapeutic doses dispensed in Oklahoma in 2009 contained 175 millicuries or more activity.

5. *In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with 1-131 in excess of the default limits home, or to a hotel?*

Records of patient release and compliance with 10 CFR 35.75 are reviewed on-site during each routine inspection. A search of our enforcement records showed no citations issued for violations of Part 35.75 since Oklahoma became an Agreement State in 2000. Please note that, based on our survey of state radiopharmacies, approximately 76% of the therapeutic doses of Iodine-131 dispensed in Oklahoma in 2009 fell below the 'default limit' of 33 millicuries specified by NUREG 1556, Volume 9, Appendix U.

6. *In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?*

   Instructions to patients may be reviewed on-site during routine inspections. The instructions are often printed on the same form containing the release assessment performed by the licensee.

7. *In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.*

   Our review of medical licensee enforcement and compliance records found no citations issued to any of our licensees for violations of Part 35.75.

8. *In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?*

   We agree with your conclusion regarding the difficulty of calculating exact exposures from released therapy patients; however, this is not the release criteria specified by 10 CFR 35.75. Instead, licensees are required to demonstrate that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem. Using the methods described in Appendix U of NUREG 1556, Volume 9, our licensees can demonstrate compliance with this requirement.

9. *Has your State ever attempted to determine how many patients treated with 1-131 are a) sent home b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?*

We do not maintain records of the number of patients released or admitted. As described above, our inspections focus on compliance with the patient release criteria in Part 35.75, rather than the number of patients admitted or released after treatment, or what those patients do after release. Inspectors may make note of this information during the inspection, but there is no regulatory requirement for Oklahoma licensees to maintain such records.

10. *In patients with doses in excess of the default limits, has your State ever attempted to determine whether these 1-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has NRC ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.*

    The scope of our inspections is limited to compliance with 10 CFR 35.75 and Appendix U of NUREG 1556, Volume 9. The Appendix details the method, adopted from National Counsel on Radiation Protection and Measurement (NCRP) Report No. 37, for calculating the limits on administered dose for patient release. This method includes certain assumptions regarding occupancy and distance from the patient. It is not clear if this is what is meant by the phrase 'living circumstances', but we do not require our licensees to meet any standards more stringent than those contained in the above regulations and guidance.

11. *What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?*

    We have no rules requiring licensees or patients to disclose any aspect of their medical treatment.

12. *Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels: If so, please provide copies.*

    We have not issued any advisories or guidance to our licensees regarding this subject. On August 6, 2007 we forwarded copies of two Information Notices from the NRC (IN 2007-03 and IN 2007-25) to all of our medical licensees. Although these both concerned therapeutic use of Iodine-131, neither addressed patient activities after release.

13. *Are your licensees required to report to you any instances in which released I-131 patients caused radiation exposure to family members or members of the public?*

    No. We are guided by the requirements of 10 CFR 20.1301(a)(1) in determining dose limits to individual members of the public. That section specifically requires licensees to exclude any consideration of dose contributions from any person administered radioactive material and released under 10 CFR 35.75.

14. *Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclides.*

To the best of our knowledge, we have not communicated with the Nuclear Regulatory Commission on this subject.

15. *Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.*

Based on our records review, we found no citations issued to any of our licensees for violations of Part 35.75, and no inspection document relating to release of a patient to a hotel after treatment.

NUCLEAR MEDICINE INSPECTION RECORD

Inspection Record No: - License No: OK- -

Licensee (Name and Address):

Licensee Contact: Telephone No: ( ) -

Priority: Program Code:

Date of Last Inspection:
Date of This Inspection:

Type of Inspection: ☐ Announced ☐ Unannounced ☐ Routine ☐ Special (describe below) ☐ Initial

Next Inspection Date: ☐ Normal ☐ Reduced ☐ Extended

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

☐ No violations cited, clear ODEQ Form 410-591 issued
☐ Non-cited violations
☐ Violation(s), Form 591 issued
☐ Violation(s), Notice of Violation issued
☐ Follow-up on previous violations

Comments:

Inspector(s) _____ Date: _____
(Signature)

(Name)

Approved _____ Date: _____
(Signature)

Mike Broderick

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES (License amendments issued since last inspection, or program changes noted in the license)

   AMENDMENT # DATE SUBJECT

2. INSPECTION AND ENFORCEMENT HISTORY: (Unresolved issues; previous and repeat violations; and orders)

3. INCIDENT/EVENT HISTORY: (List any incidents, recordable events, or mis-administrations reported to DEQ since the last inspection. Citing "None" indicates that NMED, event files, and the licensing file have no evidence of any incidents or events since the last inspection)

PART II - INSPECTION DOCUMENTATION

* References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 87115, Appendix B, "Nuclear Medicine Inspection References".

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in this part are not required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

Note: Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or the patient's privacy.

1. ORGANIZATION AND SCOPE OF PROGRAM: (Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

2. MANAGEMENT OVERSIGHT: (Management support to radiation safety; Radiation Safety Committee; Radiation Safety Officer; and program audits, including as low as is reasonably achievable (ALARA) reviews)

3. FACILITIES: (Facilities as described; uses; control of access; and engineering controls)

4. EQUIPMENT AND INSTRUMENTATION: (Dose calibrator; instrumentation for assaying alpha-emitting and beta-emitting radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation.)

5. MATERIAL USE, CONTROL, AND TRANSFER: (Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

6. RADIOPHARMACEUTICAL THERAPY: (Safety precautions; surveys; and release criteria of patients and rooms)

7. QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS: (QMP - written directives, implementation, reviews, and records; mis-administrations or identifications, notifications, reports, and records)

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL: (Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses)

9. TRAINING AND INSTRUCTIONS TO WORKERS: (Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users)

10. RADIATION PROTECTION: (Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release)

11. RADIOACTIVE WASTE MANAGEMENT: (Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; and records)

12. DECOMMISSIONING: (Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements)

13. TRANSPORTATION: (Quantities and types of licensed material shipped; packaging design requirements; hazardous materials (HAZMAT) communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

14. NOTIFICATIONS AND REPORTS: (Theft; loss; incidents; overexposures; change in Radiation Safety Officer (RSO), authorized user, or nuclear pharmacist; and radiation exposure reports to individuals)

15. POSTING AND LABELING: (Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS: (Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs) AND OTHER SAFETY ISSUES: (State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations)

18. PERSONNEL CONTACTED: (Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone)

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting
+ Individual(s) contacted by telephone

19. PERFORMANCE EVALUATION FACTORS:

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight	☐ Y ☐ N
B.	RSO too busy with other assignments	☐ Y ☐ N
C.	Insufficient staffing	☐ Y ☐ N
D.	Radiation Safety Committee (RSC) fails to meet or functions inadequately	☐ Y ☐ N ☐ N/A
E.	Inadequate consulting services or inadequate audits conducted	☐ Y ☐ N ☐ N/A

Remarks (consider the above assessment and/or other pertinent performance evaluation factors (PEFs) with regard to the licensee's oversight of the radiation safety program)

20. SPECIAL CONDITIONS OR ISSUES: (Special license conditions)

PART III - POST- INSPECTION ACTIVITIES

1. FOLLOW-UP ON PEFs:

2. DEBRIEF WITH STAFF: (Post-inspection communication with supervisor and staff)

END